Building Effective Partnerships
FDA Public Meeting

Panelist Biographies

Jane Henney
Susan Alpert
Jane Axelrad
Andrew Beaulieu
Dan Casciano
Sharon Smith Holston
Erica Jones
Tobias Massa
Charles Sizer
John Taylor
Kathy Zoon

JANE E. HENNEY, M.D.

Commissioner of Food and Drugs
Food and Drug Administration

Dr. Henney began her tenure as Commissioner of the Food and Drug Administration (FDA) in November of 1998. Prior to that, she served as the first Vice President of the University of New Mexico Health Sciences Center from 1994 to 1998. Before joining the University, Dr. Henney served as the Deputy Commissioner for Operations at FDA from 1992 to 1994. Dr. Henney's other past academic administrative positions have included Vice Chancellor for Health Programs and Policy at the University of Kansas, and Acting Director of the University of Kansas Mid America Cancer Center from 1985 to 1992. She also served as Interim Dean of the School of Medicine at the University of Kansas from 1987 to 1989. From 1976 to 1985, Dr. Henney held various positions at the National Cancer Institute (NCI) of the National Institutes of Health. From 1980-1985, Dr. Henney was Deputy Director of the NCI.

In addition to being an active member of many professional societies, Dr. Henney has been the President of the United States Pharmacopeial Convention, a member of the Advisory Committee to the Director for the National Institutes of Health, a member of the National Advisory Research Resources Council, and a member of the American Cancer Society National Board of Directors. She has served as a member of the Board of Directors of the Lovelace Respiratory Institute, the Kansas Health Foundation, and the Kansas State University Cancer Center. Dr. Henney also has served on an Advisory Committee for The Commonwealth Fund and as a consultant to the W.K. Kellogg Foundation. She has also served as a member of the Board of Trustees at Manchester College.

Dr. Henney is a graduate of Indiana University School of Medicine and Manchester College. She completed her medical internship at St. Vincent's Hospital, and her residency at Georgia Baptist Hospital. Dr. Henney was a Fellow in Medical Oncology at M.D. Anderson Hospital and Tumor Institute, and completed graduate medical work at the Cancer Therapy Evaluation Program at NCI. She has also completed management training at the John F. Kennedy School of Government at Harvard University.

In addition to other distinguished honors, Dr. Henney was recently given an Honorary Fellowship from the American College of Healthcare Executives. She also received the Indiana University Medical School Distinguished Alumni Award in 1998, the Manchester College Alumni Award in 1996, the M.D. Anderson Cancer Center Distinguished Alumnus Award, and was a member of the Leadership New Mexico Inaugural Class in 1996-1997. Dr. Henney received the Public Health Service Commendation Medal in 1979 and 1981, and the Commissioner's Special Citation in 1994. Dr. Henney has also received the Jacobs Institute's Excellence in Women's Health Award, the Public Health Leadership Award from the National Organization for Rare Disorders, and the George Crile Award from the International Platform Association.

SUSAN ALPERT, M. D., Ph.D.

Director for Food Safety
Food and Drug Administration

Dr. Alpert was selected as Director for Food Safety at the Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA), which includes responsibility as the Director of the President's Initiative for Food Safety. On January 25, 1997, President Clinton announced a new initiative to improve the safety of the food supply of the Nation. Recognizing that food safety is not simply a responsibility of the Federal government and that an effective comprehensive food safety strategy must involve partners outside the Federal Government, the President established a Council on Food Safety and directed that it work with consumers, producers, industry, states, tribes, colleges and universities, and the public to identify additional ways to improve food safety through Government and the private sector action, including public-private partnerships. Dr. Alpert is strongly committed to an open process that includes a full discussion of the wide range of issues that may be raised by our various constituencies.

Dr. Alpert's previous position was as Director of the Office of Device Evaluation (ODE) at the Center for Devices and Radiological Health, FDA. ODE is responsible for the pre-market evaluation of the safety and effectiveness of medical devices. Dr. Alpert joined the FDA in 1987 as a Medical Officer in the Division of Anti-Infective Drug Products in the Center for Drug Evaluation and Research. She also served there as a supervisor for anti-infective and dermatological drug products.

Dr. Alpert received her AB in Biology from Barnard College, Columbia University, and her Ph.D. in Medical Microbiology from New York University School of Medicine. She earned her M.D. at the University of Miami School of Medicine, trained in Pediatrics in Montefiore Hospital, Albert Einstein College of Medicine in New York, and completed her training in Pediatric Infectious Diseases at Children's Hospital in Washington, D.C. as part of a joint program with the FDA.

JANE A. AXELRAD

Associate Director for Policy, Center for Drug Evaluation and Research
Food and Drug Administration

Ms. Axelrad is the Associate Director for Policy, in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). She is responsible for managing the development of new regulations and policies applicable to the FDA's regulation of human pharmaceuticals and for responding to citizen petitions affecting human prescription pharmaceuticals. Ms. Axelrad is also responsible for managing the collection of user fees under the Prescription Drug User Fee Act of 1992, as amended by the FDA Modernization Act of 1997, and for responding to requests for waivers and refunds of those fees. Ms. Axelrad has been the Center lead on a number of agency-wide policy initiatives including the development of new environmental regulations, the

negotiation and implementation of the FDA Modernization Act, and FDA regulation of sales of drugs on the Internet.

Ms. Axelrad, who is an attorney, joined the FDA in 1991. She received her BA in Mathematics and Sociology from the University of Michigan and her JD degree from the Columbus School of Law, Catholic University of America. Before she joined the FDA, she held a series of legal and policy positions at the Nuclear Regulatory Commission and the Environmental Protection Agency. In 1997, Ms. Axelrad received the Department of Health and Human Services Secretary's Award for Distinguished Service, and, in 1998, a Presidential Rank Meritorious Executive Award. Ms. Axelrad is a member of the Food and Drug Law Institute Editorial Advisory Board.

ANDREW J. BEAULIEU, D.V.M.

Deputy Director of the Center for Veterinary Medicine,
Food and Drug Administration

Andrew J. Beaulieu, D.V.M. is Deputy Director of the Center for Veterinary Medicine, Food & Drug Administration. He was selected to serve in that position in July 1999. Prior to that selection, Dr. Beaulieu worked in CVM's Office of New Animal Drug Evaluation as a Division Director for food animal therapeutics and (for about 7 years) as a Deputy Director of the Office. He was directly involved in most of the significant changes in policy and procedures that affected new animal drug review over that period, including participating in drafting and implementing the Animal Drug Availability Act of 1996. Dr. Beaulieu joined the Center in June 1972. Most of his time prior to 1991 was spent in the Office of Surveillance and Compliance in the Division of Surveillance where he was responsible for the review of Drug Experience Reports and supporting compliance actions against marketers of unapproved new animal drugs.

Dr. Beaulieu received his DVM degree from Ohio State University in 1972 and B.S. and B. A. degrees (in biology and chemistry respectively) from the University of Miami in 1967.

DANIEL A. CASCIANO, Ph.D.

Acting Director, and Deputy Director for Research
National Center for Toxicological Research
Food and Drug Administration

Dr. Casciano received a Ph.D. degree in Cell Biology from Purdue University and was a postdoctoral fellow in Biochemistry at the University of Tennessee Biomedical Division at the Oak Ridge National Laboratories. He joined the Food and Drug Administration, National Center for Toxicological Research (NCTR), Division of Mutagenesis Research, in 1973. During his tenure at the NCTR, he has held the positions of Director, Program on Mutagenesis; Director, Division of Mutagenesis Research; Director, Division of

Genetic Toxicology; Director, Division of Genetic and Reproductive Toxicology; Deputy Director for Research; and Acting Director, NCTR. Dr. Casciano is an Adjunct Professor in the Departments of Pharmacology and Toxicology and Biochemistry and Molecular Biology, University of Arkansas for Medical Sciences.

Dr. Casciano has published more than 160 articles in peer-reviewed journals. His research interests are focused on detecting chemical-induced DNA damage and understanding how this damage is processed to a mutation. During his research career, he has utilized primary cultures of mouse, rat, and human hepatocytes to evaluate metabolism, DNA adduct formation, and repair of DNA damage when the cells were exposed to hepatocarcinogens. Efforts in this area also include measurement of carcinogen-induced gene expression using DNA microarrays. Recently, he has devoted major efforts toward development, characterization, and utilization of *in vivo* mutation models that measure spontaneous and induced mutations in native genes and transgenes. As Deputy Director for Research and Acting Director, NCTR, he plans to enhance the area of molecular toxicology at the NCTR and to utilize the data generated from the Human Genome Project to build toxicological models that would more closely predict adverse events in the human.

SHARON SMITH HOLSTON

Deputy Commissioner for International & Constituent Relations
Food and Drug Administration

As Deputy Commissioner for International and Constituent Relations, Sharon Smith Holston provides executive level policy and program direction for the Food and Drug Administration's (FDA) interactions, information exchanges and liaison activities with a variety of domestic and international external audiences. In addition, Ms. Holston is the Acting Director of FDA's Office of International Programs. She provides executive direction to the Associate Commissioner for Consumer Affairs, the Associate Commissioner for Special Health Issues, and the Director of the Office of Women's Health.

Ms. Holston's principal goal is to enhance FDA's working relationships with external organizations, to increase understanding of the Agency's operations and objectives, and to encourage appropriate collaborations on vital public health issues. She plays a key executive role in directing FDA's relationships with numerous foreign governments and international organizations, in the face of increasing global trade in FDA-regulated products. In addition, she represents the Commissioner of Food and Drugs in discussing the direction and accomplishment of external affairs activities with the Secretary of Health and Human Services (HHS) and senior HHS officials, the White House and the Congress. A native of Cleveland, Ohio, Ms. Holston received an A.B. degree from Barnard College of Columbia University, and a M.P.A. degree from the John F. Kennedy School of Government, Harvard University. She has held a variety of

positions in the FDA since joining the agency in 1972. She was appointed Deputy Commissioner in 1994.

Ms. Holston has twice been awarded the Presidential Rank of Meritorious Executive. In addition, she is the recipient of the Richard E. Greco Award from the Regulatory Affairs Professional Society; the Professional Achievement Award from the International Society for Pharmaceutical Engineering; numerous FDA awards; as well as the Department of Health and Human Services Senior Management Citation.

ERICA JONES

Sr. Medicare Beneficiary Relations Specialist
California Medical Review, Inc.

Erica Jones is the Sr. Medicare Beneficiary Relations Specialist for CMRI (California Medical Review, Inc.), she bringing with her more than 10 years of experience in the health care and managed care environments. Ms. Jones holds a bachelors degree in communications and gerontology from San Jose State University, and MPA/HS from the University of San Francisco with special emphasis in ethnogerontology (the study of ethnic aging.) Erica is a seasoned speaker who presents to diverse audiences on Medicare, Medicare Reform, Medicare Beneficiary Rights, Mammograms as an intervention to Black Women's Quality Health Care, Minority Health; Improving Access. Erica has been interviewed on "The Senior Report," the nations Leading Senior Correspondent on aging. KMIR-Palm Springs, CA, KHSI-Chico, CA, KAHI-Auburn, CA, Broadcast News-San Francisco, CA (radio news for the disabled), and KGO television, ABC, Inc.

TOBIAS MASSA, PH.D.

Executive Director
Global Regulatory Affairs
Eli Lilly and Company

Tobias Massa, Ph.D., DABT is the Executive Director of Global Regulatory Affairs and is responsible for all regulatory aspects of chemistry, manufacturing and controls for all Eli Lilly products, as well as submission coordination, labeling and medical information. He chairs the Corporate Specifications and Regulatory Information Technology Committees and is a member of the Regulatory/ Quality, New Product Launch, Development-Manufacturing Strategy, Clinical Research and Global Product Labeling Committees. He also is a member of the Continuing Legal Education implementation team, and the Global Development Quality Steering Committee.

Dr. Massa was a toxicologist at the Schering Plough Research Institute from 1978 to 1986 and was Associate Director/Group Leader in Toxicology for Pfizer from 1986 to 1990. He rejoined Schering Plough as Associate Director of Regulatory Affairs in 1990

and was most recently Senior Director of Worldwide Regulatory Affairs (Chemistry/Manufacturing/Controls) prior to joining Lilly as Director of Global Regulatory Affairs in 1998. Dr. Massa is currently chair of the Biology and Biotechnology Committee, and member of the FDAMA implementation team of the Pharmaceutical Research and Manufacturers of America. He also is the chair of the Product Quality Research Institute Steering Committee and is a member of the PQRI Board of Directors.

A native of New York City, he received his BA (cum laude) in chemistry from SUNY at Buffalo in 1972 where he was elected to Phi Beta Kappa, and earned his doctorate in biomedical sciences from the Mt. Sinai School of Medicine (CUNY) in 1978. He has been a Diplomate of the American Board of Toxicology since 1981.

CHARLES E. SIZER, PH.D.

Director
National Center for Food Safety and Technology

Dr. Sizer received a Ph.D. degree in Food Science and Nutrition from Colorado State University. He is the director of the National Center for Food Safety and Technology at the Illinois Institute of Technology in Summit, Illinois. Some of his accomplishments include administering a cooperative agreement between IIT and the US FDA to direct a consortium of industry, academia and government, and establishing a necessary criteria to evaluate the safety and efficacy of new processing and packaging techniques. He is the Chairman of the Industry Advisory Board of the National Science Foundation Center for Aseptic Processing and Packaging at North Carolina State University. Membership in other professional organization include: National Food Processors Association, Food Processors Institute, Professional Member of the Institute of Food Technology, National Council of Interstate Milk Shippers, Dairy and Food Industry Suppliers Association, and the Editorial Board of the *Journal of Packaging Technology.*

Dr. Sizer's research interests are directed toward sterilization processes, high pressure processing, aseptic packaging, flavor changes during processing and storage, nutrient retention in processed foods, protein quality and functionality in fabricated foods, natural toxicants in foods, environmental impact of packaging. He has published over 60 articles and papers. In addition, he has several patents that have been granted; method for processing a homogenous food product, process for packaging liquid food products, process and article for determining the residence time of a food particle and apparatus for sterilizing cartons.

JOHN M. TAYLOR

Senior Advisor for Regulatory Policy
Food and Drug Administration

John Taylor is the Senior Advisor for Regulatory Policy in the Food and Drug Administration's Office of Regulatory Affairs. His responsibilities include advising the Commissioner and the Associate Commissioner for Regulatory Affairs on regulatory issues that impact the agency's enforcement mission. Mr. Taylor also executes policy and directs special projects on the behalf of the Commissioner and the Associate Commissioner for Regulatory Affairs. These projects cover all aspects of food, drug, biologics, cosmetic, veterinary, and medical device compliance issues. Prior to joining the Office of Regulatory Affairs in the spring of 1999, Mr. Taylor served as a senior advisor to Commissioner David Kessler and Acting Commissioner Michael Friedman. Prior to joining the Office of the Commissioner, Mr. Taylor worked in FDA's Office of the Chief Counsel from 1991 to 1996. In the Office of the Chief Counsel he was responsible for all phases of criminal and civil litigation, involving violations of the Food, Drug, and Cosmetic Act, and other federal laws. He received his J.D. in 1991, from the College of William and Mary.

KATHRYN C. ZOON, PH.D.

Director, Center for Biologics Evaluation and Research
Food and Drug Administration

Dr. Zoon became director of the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration in March 1992. Dr. Zoon was formerly the Director of the Division of Cytokine Biology in CBER, where she was actively involved with regulatory issues related to cytokines, growth factors and studies on interferon purification, characterization and interferon receptors. Dr. Zoon worked at NIH from 1975 to 1980, with Nobel Prize Laureate Christian B. Anfinsen on the production and purification of human interferons. She continued her work in interferon and reviewed cytokine products when she joined the FDA in 1980. She received her B.S. degree, cum laude, in chemistry from Rensselaer Polytechnic Institute in 1970 and was granted a Ph.D. in biochemistry from The Johns Hopkins University in 1975.

Dr. Zoon is an editor of the Journal of Interferon Research and the author of numerous scientific papers on interferons. She serves on the Foundation for Advanced Education in the Sciences (FAES) Board of Directors as first vice president. She is a member of the NIH Scientific Directors, chair of the FDA Senior Biomedical Research Service (SBRS) Credentialing Committee, as well as the FDA representative to the DHHS SBRS Policy Board. She has received numerous awards, including BioPharm Person of the Year Award 1992, the NIH Lectureship 1994, Sydney Riegelman Lectureship 1994, Genetic Engineering News (GEN) Award 1994 for streamlining and improving the regulatory process for biologics and biotechnology products, the Meritorious Executive Rank Award 1994 for sustained superior performance in revitalizing and reorganizing

the Center for Biologics Evaluation and Research to meet the challenges of new responsibilities and new technologies, National Cancer Patients "Grateful Patients Award" 1996, Rensselaer Polytechnic Institute Alumni Association Fellows Award 1997, the Secretary's Award for Distinguished Service 1998 as a member of the FDA Reform Legislation Working Group, the 1999 Johns Hopkins University Delta Omega Alpha Chapter's 75th Anniversary Outstanding Member Award.

FDA's Leveraging

An Approach That Works

Public Education Campaign: Safe Drug Use

Each year, about half of the patients who fill the nearly 3 billion prescriptions from their doctors don't follow the proper medical regimen, and as a result, frequently endure severe consequences. In addition to human suffering, adverse drug reactions cause up to 10% of all hospital admissions and more than $76 billion in associated costs.

For women, who spend two out of every three health-care dollars, medication errors are a particularly serious hazard. Three years ago, FDA made a commitment to confront this significant public health problem. The resulting effort would bring to the nation's women the basic do's and don'ts of safe drug taking. Women's Health: Take Time To Care, FDA's grass-root campaign, was designed to deliver—primarily to women over 45 and the underserved communities—a four-point advice: (1) Read the medicine's label; (2) Don't skip doses or share medications; (3) Ask questions about your prescription; (4) Keep record of the drugs you're taking.

When FDA first tested the campaign in Hartford and Chicago, it expected to reach women with 35,000 pieces of health care material. Instead, local health and social service organizations, pharmacies, senior centers, congregations and other groups that joined the effort arranged week-long activities during which women snapped up 235,000 health-care leaflets.

The next year, FDA and its local partners brought the campaign's materials to 6,000 stores, community centers and other outlets in 14 cities and three rural areas and Native American reservations in 19 states. With the help of the National Association of Chain Drugstores (NACDS) and hundreds of local campaign partners, FDA's tips on safe medicine use reached 1.5 million people.

Last October, co-sponsored by NACDS, endorsed by the American Medical Association, and assisted by 80 national organizations, the Initiative was expanded to 20,000 drugstores and countless other locations in hundreds of towns and cities from coast to coast. In a single month, women picked up 6 million copies of FDA's safe medication tips in a handy brochure "My Medicines." Nearly 100 media outlets delivered the message to 26 million readers and viewers, and a survey has confirmed that nearly all recipients found the drug information useful.

When millions of women learn how to avoid adverse medication events, the nation's potential public health benefits are enormous. The drug stores that have participated in the FDA campaign stand to gain also. "The FDA brochures reinforce our pharmacists' message that patients have to take care to follow their medical regimens," says Phillip Schneider, director of NACDS public relations. "They're a useful tool, and making them available enhances the pharmacists' relations with the people they serve."

(For more information on Women's Health: Take Time To Care, please call Marsha B. Henderson 301-827-0350.)

FDA's Leveraging

An Approach That Works

Safer Food and Packaging

As the agency responsible for the safety of 78 percent of the national food supply—everything we eat except for meat, poultry and egg products—FDA is in a constant race to keep abreast of new food technologies and to find answers to emerging food safety problems. The issues are so complex and varied, says Dr. Jon De Vries, Senior Principal Scientist at General Mills, that solutions are beyond the means of even the large food compa nies. Yet FDA has found an approach that meets the challenge: collaborative research in two joint ventures.

FDA began to look for a food-science partnership in the late 1980s, when rapid technological advances gener ated a host of novel food processes and packaging techniques for which the agency lacked expertise. Faced with new potential health hazards, FDA turned for help to academe and industry. In 1988, the Illinois Institute of Technol ogy (IIT) responded by establishing on its Moffett campus near Chicago the National Center for Food Safety and Technology. Along with FDA, the so-called Moffet Center was joined by the University of Illinois and 70 members of the food industry.

The first American institution of its kind, the Moffett Center has focused on collaborative studies emphasizing the safety of food processing and packaging technologies and related outreach. Since the results are made available to public health agencies, food firms and academic institutes, the benefits of the research are well in excess of poten tial input into FDA guidelines, rules and policies.

Among the scores of Moffett research projects, several stand out for particularly significant contributions to the public health. For example, the scientists at Moffett Center have developed processing techniques to prevent contami nants in sprouts and fresh apple juice. Other important recent research at Moffett is expanding choices of packaging materials for use with meats to be irradiated, a highly effective technique for eliminating pathogenic microorganisms.

"Whatever resources industry contributes to the joint research is money well spent," says Dr. DeVries, who has long been involved in Moffett activities. "The projects cover a broader area than any firm could handle by itself; they attract outstanding scientists; and they improve the understanding between FDA and industry about each other's concerns."

The success of Moffett encouraged FDA to join the University of Maryland in 1996 to establish an institute to provide scientific information for safe and wholesome food supply and promote efficient use of research, education and outreach resources.

In addition to joint multidisciplinary programs between FDA and UM, the Joint Institute for Food Safety and Ap plied Nutrition (JIFSAN) provides the foundation for partnerships with other federal and state agencies, academic in stitutions, private industry, consumer and trade groups, and international organizations. The new headquarters for FDA's Center for Food Safety and Applied Nutrition is being located near the University, which will facilitate sharing of scientific resources through JIFSAN.

Risk analysis is at the top of JIFSAN's agenda. The Institute manages the Risk Assessment Consortium and the Risk Analysis Clearinghouse of the Food Safety Initiative, and has been designated by the World Health Organiza tion a Collaborating Center for Food Safety Risk Assessment.

(To find out more about FDA's food safety partnerships, please call Karen Carson 202-205-4064 (Moffett) or Samuel W. Page 202-205-2276 (JIFSAN).)

FDA's Leveraging

An Approach That Works

Better Mammograms

At the start of the 1990's, American mammography was far from reaching its potential as the best defense against breast cancer, a disease that in the U.S. strikes 180,000 women a year.

The industry record was clouded by a 1985 survey that had found problems with the quality of mammograms, and a 1992 Senate hearing documenting many other shortcomings. The American College of Radiology (ACR) had attempted to raise the standards, but only 42 percent of all mammography facilities joined its voluntary accreditation program in the first five years. The lack of a comprehensive statutory authority left the nation's 10,000 mammography facilities subject to a patchwork of largely inadequate federal, state and private requirements.

The passage of the Mammography Quality Standards Act (MQSA) in 1992 addressed these problems by mandating FDA to establish uniform high standards for the facilities, their equipment, the training of their personnel and the quality of mammograms, and by limiting the mammography practice to certified establishments that met the new requirements. Once the law authorized the urgently needed remedies, FDA—with the help of many allies—implemented them within MQSA's demanding deadline of less than two years.

A major contribution to FDA's success was ACR's program for voluntary standards and accreditation, which the agency made mandatory while working out its own exacting regulations. ACR also agreed to accredit qualifying facilities for FDA's certification, a task now carried out by five organizations. Crucial early assistance was also provided by state health authorities that, among other activities, sent their specialists to FDA's mammography inspector training seminars.

Consumer representatives, patient advocates, and health care specialists rallied behind FDA's efforts by submitting 8,000 comments on the agency's proposed final mammography rules. After additional input from experts on the National Mammography Quality Advisory Committee, FDA finalized new regulations that substantially raised the standards for the industry.

Since then, FDA has entered into a partnership with the National Cancer Institute to direct women and health care professionals to the certified facilities over a hotline. Currently, FDA is asking 350 cancer advocacy groups to distribute its brochure "Mammography Today" describing the rights of mammography patients under the FDA rule. In addition, the agency is preparing an outreach to minority women, including African Americans, Hispanics and senior citizens.

The results of these prodigious leveraging efforts have been encouraging. In fiscal year 1995, the first round of annual facility inspections found 2.6% of them seriously out of compliance with the regulations; three years later, despite the introduction of more demanding requirements, the corresponding figure was 1.1%.

"This program is an important component in the arsenal for fighting breast cancer," said Fran Visco, president of the National Breast Cancer Coalition, a grassroots organization. Before MQSA, she pointed out, "the burden fell to each woman to obtain high quality mammography services. Today, we have a national program in place that requires all facilities to meet the same standards."

(For more information about this leveraging program, please call Helen Barr 301-827-0884.)

FDA's An Approach That Works

Leveraging

High Quality Medicines

In the mid-1990s, rapid advances in manufacturing processes brought FDA and the pharmaceutical industry face to face with an increasingly pressing question of great public health importance: how to ensure high quality of medications while accommodating vital changes in production technology? FDA's first step to find a solution was to join the American Association of Pharmaceutical Scientists (AAPS) and the United States Pharmacopoeia in a series of workshops that highlighted the need for research about the nature of the problem.

This led to Step Two, a combined effort by FDA, the University of Maryland and industry to accumulate data on the impact of scale-up, formulation, and other manufacturing innovations on product quality. The success of this program prompted Step Three: a decision by FDA and representatives of the industry to create a neutral forum where the agency, academia and manufacturers could combine their resources to conduct research that would advance their mutual interests.

The outcome was the formation late last year of a non-profit corporation called The Product Quality Research Institute, Inc. (PQRI).

FDA has very high hopes for the Institute's future contribution to the public health. PQRI has an exceptionally broad base of eight founding members: AAPS; the Generic Pharmaceutical Industry Association; the National Association of Pharmaceutical Manufacturers; the National Pharmaceutical Alliance; the Consumer Healthcare Products Association; the Parental Drug Association; the Pharmaceutical Research and Manufacturing Association; and FDA. In addition, provisions have been established to enable other qualifying organizations to join the Institute.

The organizational structure of PQRI, which includes a board of directors, a priority-setting steering committee, several technical committees and numerous planned working groups, is specifically designed to marshal the experience and energies of scores of private sector, academic and government specialists. The resulting research is expected to advance the public health as well as the regulatory and pharmaceutical sciences.

Most promising of all, PQRI has a stimulating agenda focused on generating scientific information that will be made public. The plans call for projects that—among others—will improve the industry's progress in developing new drug delivery systems and quality pharmaceutical products. FDA will learn how to identify and evaluate the risks of these processes and how to upgrade the efficiency of the agency's responses.

The work of the Institute should contribute to accelerating and ensuring the availability of high quality medicines for the nation's patients, which is one of FDA's major goals. The expectations of FDA's partners in the PQRI are also high. "We see this as an opportunity to identify, discuss, and find with FDA joint solutions to key questions about product quality," says Dr. Tobias Massa, global director regulatory affairs of Eli Lilly and Co., who is the chairman of the PQRI steering committee.

(To learn more about PQRI, please call Helen N. Winkle 301-594-2847.)

Leveraging

Global Eye on Counterfeits

The great upsurge of global trade in recent years has been a blessing for consumers, by enriching their lives with an unprecedented volume and variety of products from all over the world.

For FDA and some of its foreign counterparts, however, this growing menu of new products has added an enormous burden to their already badly strained capacity for the surveillance of imported regulated goods. The new demands have been particularly hard on the regulatory authorities' forensic laboratories that bear the critical responsibility for identifying active drug ingredients and herbal products that are counterfeit, unapproved, or dangerous to health.

By the mid-90's, the combination of dire need for an effective worldwide product surveillance and the regulators' inadequate resources cried out for a novel solution. The challenge was met by a handful of FDA forensic scientists and their British colleagues who jointly created an effective international leveraging partnership.

The informal collaboration started in 1994, when the new head of laboratory testing in the United Kingdom's Medicines Control Agency (MCA) visited FDA's forensic laboratories, and was struck by the duplication of laboratory work that was carried on by FDA and his own agency. Faced with the same resource limitations and the same questions about the safety of certain products, he and his FDA colleagues agreed to divide their workload. After a return visit by an FDA scientist to MCA, lab experts in the two agencies began sharing data from their product analyses and exchanging reliable methods for the detection of harmful products and counterfeits.

Before long, the word of FDA's and MCA's resource savings and improved efficiency spread throughout the international regulatory community, and the network of collaborating lab experts began to widen. By 1996, scientists of the German, Canadian and Australian regulatory authorities joined the workload sharing and information exchanges; their Dutch and Swiss counterparts followed about a year later. The members of the network strengthened their cooperation through working visits. An Australian lab specialist recently spent six weeks helping his FDA colleagues to develop a methodology for an important antiviral drug. Two German scientists are visiting FDA's facilities at present.

Over the years, FDA forensic scientists and their foreign partners have jointly analyzed more than 20 active ingredients and other harmful or counterfeit products, and in some cases prevented their marketing—an effort that would have been beyond the resources of any one of the participating agencies. Legitimate industry benefited also, by getting rid of illegal competition that otherwise could reach significant proportions.

But Roger Alexander, the head of MCA's Good Laboratory Practices Monitoring Forensic Authority in London, believes that the real winner has been the public in the participating countries. Watching the partnership at work since its beginning, he says, left no doubt in his mind that "consumers in Europe, the U.S. and many other parts of the world are safer because we're able to work together."

(To learn more about this initiative, please call Frederick L. Fricke, Jr., 513-679-2700.)

FDA's Leveraging

An Approach That Works

Guidance for Engineers

One of FDA's closest and most productive partnerships got its start, oddly enough, in a misunderstanding. Five years ago, leading members of the International Society of Pharmaceutical Engineering noticed that the construction boom in the pharmaceutical industry which was then underway in many parts of the world frequently involved considerable waste. Because of their misunderstanding of FDA's expectations and requirements, many of ISPE's 12,000 members were building unnecessarily expensive new plants and enhancements—and the obvious remedy, the development of more explicit FDA guidelines, was beyond the agency's resources.

The ISPE's solution was to offer to write its own baseline guides if FDA would review them for accuracy. FDA promptly agreed, and the joint project by now has produced three widely used ISPE construction guides, with seven more in the works. That, however, was only the first step the two organizations have taken together to meet FDA's public health expectations. The next one took place after FDA issued a new guidance for the safe design and execution of scale-up and post-approval changes (SUPAC) in drug production. The document, which had to be prepared on a very modest budget, repeatedly allowed the use of specified or "similar" equipment, without identifying precisely what "similar" meant.

This time, it was FDA that requested ISPE's help, and the engineering group agreed to carry out— for free and under the agency's guidance—the voluminous research to assemble the necessary data. That program, on which 60 industry engineers worked for four months, produced addenda to three SUPAC guidelines, each listing hundreds of pieces of equipment that met the agency's definition of "similar."

The jointly developed ISPE guides and SUPAC addenda, says Robert Best, the president of ISPE, have made the industry better informed, and made pharmaceutical construction much less expensive. "We can safely say that the cooperation with FDA has saved the pharmaceutical industry millions of dollars," he says. "Moreover, we have learned that FDA is neither remote nor antagonistic: it can be approached, and it listens."

FDA's cooperation with ISPE goes well beyond the development of more effective regulatory documents. Last October, the two organizations held their first joint training workshops for the engineering community and FDA's plant investigators. In addition, FDA specialists have been invited to discuss the U.S. public health standards in ISPE's training sessions for pharmaceutical engineers in Brazil, the Pacific Rim countries and throughout Europe.

Sharon Smith Holston, FDA's Deputy Commissioner for International and Consumer Relations, recently expressed FDA's appreciation for ISPE's cooperation. "In today's global environment, where people and goods move across borders with minimal obstacles and in huge numbers, public health improvements anywhere in the world strengthen consumer protection in this country," she told an ISPE conference. "Your training programs abroad help FDA accomplish its very challenging task of meeting the expectations of our public, of Congress, and our own."

(For more information about this leveraging initiative, please call Joseph X. Phillips 215-597-4390, ext. 4002)

FDA's Leveraging

An Approach That Works

Center for Drug Evaluation & Research
Janet Woodcock, M.D.
Director
5600 Fishers Lane
HFD 1
Rockville, MD 20857
Tel (301) 594-5400
Fax (301) 594-6197

Center for Biologics Evaluation & Research
Kathryn C. Zoon, Ph.D.
Director
1401 Rockville Pike
HFM 1
Rockville, MD 20852
Tel (301) 827-0548
Fax (301) 827-0440

Center for Food Safety & Applied Nutrition
Joseph A. Levitt
Director
200 C St., SW
HFS 1
Washington, D.C. 20204
Tel (202) 205-4850
Fax (202) 205-5025

Center for Devices & Radiological Health
David W. Feigal, Jr., M.D., M.P.H.
Director
9200 Corporate Blvd
HFZ 1
Rockville, MD 20850
Tel (301) 443-4690
Fax (301) 594-1320

National Center for Toxicological Research
Daniel A. Casciano, Ph.D.
Acting Director
NCTR Drive
HFT 120
Jefferson, AR 72079
Tel (870) 543-7516
Fax (870) 543-7576

Center for Veterinary Medicine
Stephen Sundolf, D.V.M., Ph.D.
Director
7500 Standish Place
HFV 1
Rockville, MD 20857
Tel (301) 594-1740
Fax (301) 594-1830

Office of International & Constituent Relations
Sharon Smith Holston
Deputy Commissioner
5600 Fishers Lane
HF 24
Rockville, MD 20857
Tel (301) 827-3450
Fax (301) 827-1335

Office of Regulatory Affairs
Dennis Baker
Director
5600 Fishers Lane
HFC 1
Rockville, MD 20857
Tel (301) 827-3101
ax (301) 443-6591

Guiding Principles for Leveraging at FDA

By choosing to work with other organizations that share our public health and safety goals, FDA can significantly amplify its public health impact, leverage the intellectual capital of others, and make wise use of its resources. FDA has been quite successful with its past collaborations and the agency intends to expand and build upon this solid foundation in developing new partnerships.

What is leveraging? Leveraging is the creation of relationships and/or formal agreements with others outside the FDA that will ultimately enhance FDA's ability to meet its public health mission. Leveraging is a continuum.

The guiding principles for leveraging at FDA are:

1. Leveraging can produce greater net benefits, e.g., by sharing talent and material resources and achieving results through synergism.

2. Successful leveraging provides benefits and incentives for all participants. In addition to FDA this may include consumers, industry, academia, health providers, and other government agencies. In particular, leveraging efforts should increase consumer confidence in regulated products.

3. Successful leveraging requires
   - identification of tasks to be accomplished
   - identification of partners with whom we share goals
   - agreement on the roles of each partner in accomplishing those tasks
   - shared responsibility for obtaining and evaluating results
   - an open and credible process for those parties involved
   - recognizing accomplishments

4. Leveraging must work within established FDA legal authority.

5. FDA's status as a scientific regulatory agency requires an added dimension of due diligence and management of leveraged relationships by professionals at all levels within the agency.

6. Leveraging activities should not
   - compromise the Agency's commitment to high standards in terms of timeliness, predictability, and quality of our science and decision making,
   - jeopardize FDA's role as an independent, impartial scientific agency,
   - result in the occurrence or the appearance of a conflict of interest, or
   - be seen as a means to avoid or off-load work and responsibilities or merely as a response to an inadequate budget.

7. Leveraging can be accomplished through a wide variety of collaborative arrangements, both formal and informal.

How Will FDA Look in Five Years In Regard to Outside Leveraging?

- **Seeking out partners with shared interests** -- FDA will look first to those with shared interests to assist in addressing emerging issues or concerns. We will move away from "FDA first and only" and toward an approach that also seeks out willing and capable partners.
- **Considering partners early in the process** -- All staff throughout FDA, when recognizing an issue or concern, will first ask, "Who, in addition to FDA, shares an interest in addressing this?"
- **Developing courses of action together** -- FDA will vigorously pursue collaborations from the first stages of identifying a shared issue or concern, devising possible solutions, and selecting the most expeditious and efficient course of action.
- **Defining the broader issues** – FDA will share its knowledge to help define critical public health issues even if FDA has little or no direct responsibility for addressing that issue today.
- **Partners seek-out FDA's involvement** -- Partners from industry, health providers, academia, other government agencies, and consumer groups will bring problems of public health significance to FDA and eagerly work together to solve them.
- **Partners and FDA contacts** – A compendium of potential partners will be maintained to enable expeditious leveraging.
- **Partnerships yield long-term benefits** -- Outside leveraging opportunities will provide long term remedies to some of the most complex public health issues facing the Agency.
- **Increased consumer confidence** – Leveraging efforts will increase consumer confidence in FDA's public health protection role.
- **Commitment to mutual recognition** -- When describing or reporting successes through collaboration, FDA and any partners will expressly recognize each other's contributions.

FDA's Current Vision Supports a Leveraging Commitment

The following components of FDA's Vision Statement support outside leveraging.

FDA is:

- **An enabling agency**—it stewards needed products and promotes public health.
- **A collaborative agency**—it strengthens its ties to the domestic and international scientific, health provider, and regulatory communities.
- **A high-performance agency**—it capitalizes on state-of-the-art information and communication technologies and management systems to enhance performance.